



DAE ZIW

Atty. Dkt. No. 077281-0104

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Hortense W. DODO, *et al.*

Title: DOWN-REGULATION AND SILENCING OF ALLERGEN  
GENES IN TRANSGENIC PEANUT PLANTS

Patent No.: 6,943,010

Grant Date: September 13, 2005

Appl. No.: 09/715,036

Filing Date: November 20, 2000

Examiner: Terra C. GIBBS

Art Unit: 1635

**REQUEST FOR RECONSIDERATION OF**  
**PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705**

Attn: Petitions  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.705, Applicants respectfully request reconsideration of the Patent Term Adjustment (PTA) to read 309 days, as opposed to the 189 days of PTA as indicated in the Letters Patent No. 6,943,010 granted September 13, 2005. Since November 13, 2005 fell on a Sunday, this request is considered timely as it is filed on the next business day, November 14, 2005.

Attached please find a copy of the first page of Letters Patent No. 6,943,010 granted September 13, 2005, and a computer printout of the PTA History from the PAIR system dated November 14, 2005. In addition, attached is a copy of the Decision on Application for Patent Term Adjustment mailed July 14, 2005.

Although the Patent Term Adjustment is listed as 189 days, our investigation indicates that the proper PTA should be 309 days. Accordingly, Applicants disagree with the determination of Patent Term Adjustment, and present the following facts to support their contention that the patent term reward should be 309 days instead of 189 days.

**Bases for the Adjustment** – Applicants believe that the calculation of Applicants' Total Delay is incorrectly set forth as 352 days instead of 148 days as indicated by our Patent Term Adjustment Calculation System (a copy of which is attached).

As decided in the PTO Decision on Application for Patent Term Adjustment mailed July 14, 2005, the correct determination of patent term adjustment *at the time of allowance* was 52 days (200 days of PTO delay, reduced by 148 (91+28+29) days of Applicant Delay).

From the time of allowance through the grant date of the Letters Patent for this application, the Applicant has not caused any additional days of delay. The Request for Reconsideration of Patent Term Adjustment filed concurrently with submission of the Issue Fee payment on August 30, 2004, does not cause substantial interference and delay in the patent issue process as this submission does not fall under 37 C.F.R. § 1.704. Accordingly, the total days of Applicant delay *at the time of the Letters Patent granting* remains 148 days.

However, from the time of allowance through the grant date of the Letters Patent for this application, the PTO has caused an additional 257 days delay, by not granting the Letters Patent within four (4) months time from the date the Issue Fee was paid. Applicants submitted payment of the Issue Fee on August 30, 2004, and the Letters Patent granted on September 13, 2005. As a result, the total days of PTO delay *at the time of the Letters Patent granting* is 457 (200 + 257) days delay.

Therefore, the Applicants believe that the PTO's calculation of Patent Term Adjustment is in error, and request that the Applicants be granted an additional 120 days of patent term. The corrected Patent Term Adjustment should be 309 days (457 (200+257) days of PTO delay, reduced by 148 (91+28+29) days of Applicant Delay).

**Statements Pursuant to 37 C.F.R. § 1.705(b)(2)(iii) and (iv)** - This application is not subject to a terminal disclaimer, and there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

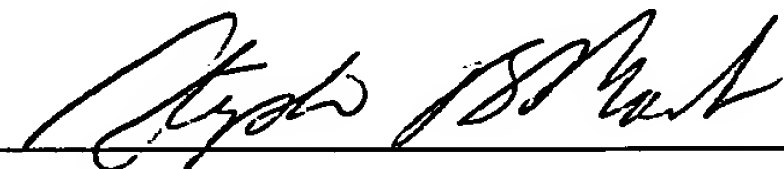
This request is being filed within two months time of the Letters Patent granting, and attached with this request is a check for payment of the statutory fee of \$200.00 as set forth in 37 C.F.R. § 1.18(e). Since November 13, 2005 fell on a Sunday, this request is considered timely as it is filed on the next business day, November 14, 2005.

Applicants' further request that the PTO consider refunding the submitted statutory fee of \$200.00, since this is the *second* Request for Reconsideration of Patent Term Adjustment filed with the PTO *due to the PTO's error* in calculating the Patent Term Adjustment incorrectly.

Furthermore, the Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date Nov. 14, 2005

By 

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US006943010B1

(12) **United States Patent**  
**Dodo et al.**

(10) **Patent No.:** **US 6,943,010 B1**  
(45) **Date of Patent:** **Sep. 13, 2005**

(54) **DOWN-REGULATION AND SILENCING OF ALLERGEN GENES IN TRANSGENIC PEANUT SEEDS**

(76) Inventors: **Hortense W. Dodo**, 1828 Sparkman Dr., Huntsville, AL (US) 35816; **Charles J. Arntzen**, 1005 Highland Rd., Ithaca, NY (US) 14850-1447; **Olga Martha Viquez**, 4515 Bonnell Dr., Apt. 2G, Huntsville, AL (US) 35816; **Koffi N'da Konan**, 801 Julia St., #D, Huntsville, AL (US) 35816

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 189 days.

(21) Appl. No.: **09/715,036**  
(22) Filed: **Nov. 20, 2000**

**Related U.S. Application Data**

(60) Provisional application No. 60/167,255, filed on Nov. 19, 1999.

(51) Int. Cl.<sup>7</sup> ..... **C12N 15/00**  
(52) U.S. Cl. .... **435/320.1; 800/298; 435/419; 435/468**  
(58) Field of Search ..... **435/6; 514/44; 536/23.1, 24.5; 800/286, 295, 278**

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

4,376,110 A	3/1983	David et al.
4,407,956 A	10/1983	Howell
4,458,066 A	7/1984	Caruthers et al.
5,026,545 A	6/1991	Saint-Remy et al.
5,558,869 A	9/1996	Burks, Jr. et al.
5,917,127 A	6/1999	Willmitzer et al.
5,951,984 A	9/1999	Kaneko et al.

**FOREIGN PATENT DOCUMENTS**

EP	0116718	8/1984
EP	0242246	10/1987
WO	84/02913	8/1984

WO 99/38978 8/1999

**OTHER PUBLICATIONS**

Krapovickas, A. Domestication and exploitation of plants and animals. London: Gerald Duckworth, 1969:247.\*  
Lacorte et al. Gene transfer into peanut (*Arachis hypogaea* L.) by *Agrobacterium tumefaciens*. Plant Cell Reports, 1991 vol. 10:354-357.\*  
Klein et al. High-velocity microprojectiles for delivering nucleic acids into living cells. Nature, 1987, vol. 327:70-73.\*

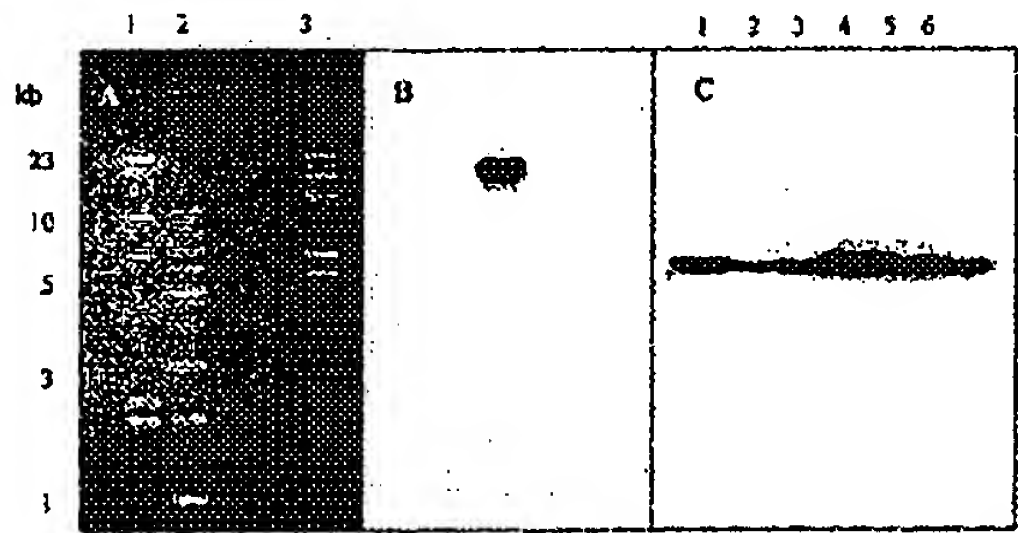
(Continued)

*Primary Examiner*—Karen A. Lacourciere  
*Assistant Examiner*—Terra C. Gibbs  
(74) *Attorney, Agent, or Firm*—Foley & Lardner LLP

(57) **ABSTRACT**

An allergen-free transgenic peanut seed is produced by recombinant methods. Peanut plants are transformed with multiple copies of each of the allergen genes, or fragments thereof, to suppress gene expression and allergen protein production. Alternatively, peanut plants are transformed with peanut allergen antisense genes introduced into the peanut genome as antisense fragments, sense fragments, or combinations of both antisense and sense fragments. Peanut transgenes are under the control of the 35S promoter, or the promoter of the Ara h2 gene to produce antisense RNAs, sense RNAs, and double-stranded RNAs for suppressing allergen protein production in peanut plants. A full length genomic clone for allergen Ara h2 is isolated and sequenced. The ORF is 622 nucleotides long. The predicted encoded protein is 207 amino acids long and includes a putative transit peptide of 21 residues. One polyadenylation signal is identified at position 951. Six additional stop codons are observed. A promoter region was revealed containing a putative TATA box located at position -72. Homologous regions were identified between Ara h2, h6, and h7, and between Ara h3 and h4, and between Ara h1P41B and Ara h1P17. The homologous regions will be used for the screening of peanut genomic library to isolate all peanut allergen genes and for down-regulation and silencing of multiple peanut allergen genes.

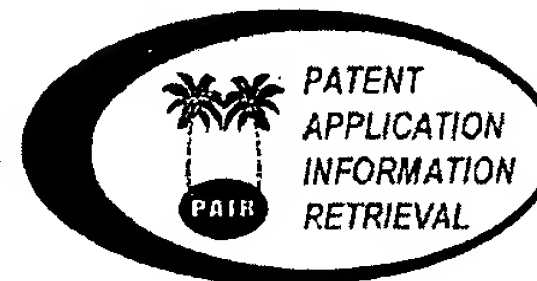
8 Claims, 9 Drawing Sheets



(A) *Bam* HI digestion pattern of positive 50kb lambda clone for Ara hII gene (lane3), Lambda DNA/*Hind* III markers (lane1), 1 kb DNA step ladder (lane2). (B) Hybridization of a 60-mer labeled probe with an subcloned 12kb *Bam* HI-fragment. (C) Hybridization of an 62-mer labeled probe with a subcloned 6.5 *Bam* HI-fragment (clones 1-6).



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**PATENT APPLICATION INFORMATION RETRIEVAL**

Patent Term Adjustment (PTA) for publication number: 09/715,036			
			Days
Filing or 371(c) Date:	11-20-2000	USPTO Delay (PTO):	457 ✓
Issue Date of Patent:	09-13-2005	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL):	352 -148
Post-Issue Petitions (days):	+0	Total PTA:	189 309
USPTO Adjustment (days):	+84	Explanation of Calculations	

## Search Options

Continuity Data
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Maintenance Fees - View payment windows
Maintenance Statement - View 04 year payment window
Maintenance Statement - View 08 year payment window
Maintenance Statement - View 12 year payment window
Published Documents

Maintenance Fees Available: Mon-Fri 5:30 AM to Midnight, Sat-Sun-Hol. 7:30 AM to 8:00 PM E.T.

Patent Term Adjustment History			
Date	Contents Description	PTO (days)	APPL (days)
08-24-2005	PTA 36 Months		
09-13-2005	Patent Issue Date Used in PTA Calculation	257	
08-12-2005	Receipt into Pubs	↑	
08-12-2005	Receipt into Pubs	↑	
08-12-2005	Dispatch to FDC	↑	
08-12-2005	Application Is Considered Ready for Issue	↑	
08-30-2004	Issue Fee Payment Verified	↑	
07-19-2005	Receipt into Pubs		
07-14-2005	Record a Petition Decision of Granted for Patent Term Adjustment after Allowance		
07-13-2005	Adjustment of PTA Calculation by PTO		
07-13-2005	Adjustment of PTA Calculation by PTO		
07-13-2005	Adjustment of PTA Calculation by PTO		
07-13-2005	Adjustment of PTA Calculation by PTO		
08-30-2004	Petition Entered		
08-30-2004	Miscellaneous Incoming Letter		120 ?
03-23-2005	Receipt into Pubs		
01-06-2005	Receipt into Pubs		

08-30-2004	Applicant Has Filed a Verified Statement of Small Entity Status in Compliance with 37 CFR 1.27		
09-13-2004	Receipt into Pubs		
08-30-2004	Workflow incoming petition IFW		
08-30-2004	Issue Fee Payment Received		
08-05-2004	Mail Miscellaneous Communication to Applicant		
08-03-2004	Miscellaneous Communication to Applicant - No Action Count		
07-19-2004	Sequence Forwarded to Pubs on Tape		
06-14-2004	Workflow - File Sent to Contractor		
06-02-2004	Mail Notice of Allowance		
05-28-2004	Notice of Allowance Data Verification Completed		
05-28-2004	Case Docketed to Examiner in GAU		
03-22-2004	Date Forwarded to Examiner		
03-17-2004	Response after Non-Final Action		
02-20-2004	Mail Non-Final Rejection		
02-18-2004	Non-Final Rejection		
12-17-2003	Date Forwarded to Examiner		
12-04-2003	Request for Continued Examination (RCE)		91
12-17-2003	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		↑
12-04-2003	Workflow - Request for RCE - Begin		↑
10-15-2003	Mail Advisory Action (PTOL - 303)		↑
10-14-2003	Advisory Action (PTOL-303)		↑
10-06-2003	Date Forwarded to Examiner		↑
09-25-2003	Amendment after Final Rejection		↑
09-25-2003	Request for Extension of Time - Granted		↑
06-04-2003	Mail Final Rejection (PTOL - 326)		↑
05-31-2003	Final Rejection		
03-06-2003	Information Disclosure Statement (IDS) Filed		
03-20-2003	Date Forwarded to Examiner		
03-06-2003	Response after Non-Final Action		28
03-06-2003	Request for Extension of Time - Granted		↑
11-06-2002	Mail Non-Final Rejection		↑
11-04-2002	Non-Final Rejection		
10-15-2002	Date Forwarded to Examiner		
10-08-2002	Response to Election / Restriction Filed		
10-08-2002	Request for Extension of Time - Granted		
08-08-2002	Mail Restriction Requirement	200	
08-08-2002	X-Post-Legal Complete Rejection	↑	
08-08-2002	Requirement for Restriction / Election	↑	
05-22-2002	Case Docketed to Examiner in GAU	↑	
02-20-2002	X-Pre-Legal Complete New Case	↑	
12-10-2001	Case Docketed to Examiner in GAU	↑	
12-06-2001	Case Docketed to Examiner in GAU	↑	
10-26-2001	Information Disclosure Statement (IDS) Filed	↑	
09-18-2001	Information Disclosure Statement (IDS) Filed	↑	
05-18-2001	Preliminary Amendment	↑	
11-06-2001	Case Docketed to Examiner in GAU	↑	
08-21-2001	Application Dispatched from OIPE	↑	
08-10-2001	Application Is Now Complete	↑	113

08-06-2001	Correspondence Address Change	↑	↑
06-21-2001	CRF Is Good Technically / Entered into Database	↑	↑
01-19-2001	Notice Mailed--Application Incomplete--Filing Date Assigned	↑	↑
01-19-2001	Correspondence Address Change	↑	
12-12-2000	IFW Scan & PACR Auto Security Review	↑	
11-20-2000	Initial Exam Team nn	↑	





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**OFFICE OF PETITIONS**

In re Application	:
Dodo, et al.	:
Application No. 09/715,036	: DECISION ON APPLICATION
Filed: November 20, 2000	: FOR PATENT TERM ADJUSTMENT
Atty Docket No. 077281-0104	:

This is a decision on the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. §§ 1.705", filed August 30, 2004. Applicants request that the initial determination of patent term adjustment under 35 U.S.C. 154(b) be corrected from zero (0) days to fifty-two (52) days.

The application for patent term adjustment is GRANTED.

The Office has updated the PAIR screen to reflect that the correct Patent Term Adjustment (PTA) determination at the time of the mailing of the Notice of Allowance is **fifty-two (52) days**. A copy of the updated PAIR screen, showing the correct determination, is enclosed.



On June 2, 2004, the Office mailed the Determination of Patent Term Adjustment under 35 U.S.C. 154(b) in the above identified application. The Notice stated that the patent term adjustment (PTA) to date is zero (0) days. On August 30, 2004, Applicants timely<sup>1</sup> submitted the instant application for patent term adjustment, asserting that the correct number of days of PTA at the time of the mailing of the Notice of Allowance is fifty-two (52) days.

Applicants assert entitlement to a patent term adjustment of fifty-two (52) days on the basis that the PTO improperly assessed Applicants a delay of one hundred thirteen (113) days for responding to a Notice to File Missing Parts mailed on January 19, 2001. Applicants assert that they filed a complete response on May 18, 2001, and as such should only have been assessed delay of twenty-nine (29) days.

Applicants state that the patent issuing from the application is not subject to a terminal disclaimer.

The Office initially determined a patent term adjustment of zero (0) days based on an adjustment for PTO delay of two hundred (200) days pursuant to 35 U.S.C. 154(b)(1)(A)(i) and 37 C.F.R. § 1.703(a)(1), reduced by Applicants' delays of one hundred thirteen (113), twenty-eight (28), and ninety-one (91) days pursuant to 35 U.S.C. 154(b)(2)(C)(ii) and 37 C.F.R. § 1.704(b). The adjustment of one hundred thirteen (113) days is at issue.

The adjustment of one hundred thirteen (113) days has been found to be incorrect. A review of the application file reveals that a Notice to File Missing Parts of Nonprovisional Application was mailed on January 19, 2001. Applicants filed a complete response to this notice on May 18, 2001. As this was not timely pursuant to 37 C.F.R. § 1.704(b), applicant delay of twenty-nine (29) days should have been assessed, not one hundred thirteen (113) days.

In view thereof, the correct determination of patent term adjustment at the time of the mailing of the Notice of Allowance is **fifty-two (52) days** (200 days of PTO delay, reduced by 148 (91+28+29) days of applicant delay).

Receipt of the \$200.00 fee set forth in 37 C.F.R. § 1.18(e) is acknowledged.

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<sup>1</sup> Applicants filed the application for patent term adjustment together with the payment of the issue fee.

The application file is being forwarded to the Office of Patent Publication for processing into a patent.

Telephone inquiries specific to this matter should be directed to Cliff Congo, Petitions Attorney, at (571)272-3207.

*Karin Ferriter*  
*yes*

Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of Deputy Commissioner  
for Patent Examination Policy

Enclosure: Copy of Revised PAIR Screen

Day : Wednesday

Date: 7/13/2005

Time: 14:04:20

**PALM INTRANET****PTA Calculations for Application: 09/715036**

Application Filing Date:	11/20/2000	PTO Delay (PTO):	200
Issue Date of Patent:		Three Years:	0
Pre-Issue Petitions:	0	Applicant Delay (APPL):	232
Post-Issue Petitions:	0	Total PTA (days):	52
PTO Delay Adjustment:	84		

**File Contents History**

Number	Date	Contents Description	PTO	APPL	START
62	07/13/2005	ADJUSTMENT OF PTA CALCULATION BY PTO		29	
61	07/13/2005	ADJUSTMENT OF PTA CALCULATION BY PTO	113		
48	06/02/2004	MAIL NOTICE OF ALLOWANCE			
47	05/28/2004	ISSUE REVISION COMPLETED			
46	05/28/2004	NOTICE OF ALLOWANCE DATA VERIFICATION COMPLETED			
45	05/28/2004	CASE DOCKETED TO EXAMINER IN GAU			
44	05/28/2004	NOTICE OF ALLOWABILITY			
43	03/22/2004	DATE FORWARDED TO EXAMINER			
42	03/17/2004	RESPONSE AFTER NON-FINAL ACTION			
41	02/20/2004	MAIL NON-FINAL REJECTION			
40	02/18/2004	NON-FINAL REJECTION			
39	12/17/2003	DATE FORWARDED TO EXAMINER			
38	12/04/2003	REQUEST FOR CONTINUED EXAMINATION (RCE)		91	30
37	12/17/2003	DISPOSAL FOR A RCE/CPA/129 (EXPRESS ABANDONMENT IF CPA)			
36	12/04/2003	WORKFLOW - REQUEST FOR RCE - BEGIN			
35	10/15/2003	MAIL ADVISORY ACTION (PTOL - 303)			
34	10/14/2003	ADVISORY ACTION (PTOL-303)			
33	10/06/2003	DATE FORWARDED TO EXAMINER			
32	09/25/2003	AMENDMENT AFTER FINAL REJECTION			
31	09/25/2003	REQUEST FOR EXTENSION OF TIME - GRANTED			
30	06/04/2003	MAIL FINAL REJECTION (PTOL - 326)			
29	05/31/2003	FINAL REJECTION			
28	03/06/2003	INFORMATION DISCLOSURE STATEMENT (IDS)		0	26

		FILED			
27	03/20/2003	DATE FORWARDED TO EXAMINER			
26	03/06/2003	RESPONSE AFTER NON-FINAL ACTION		28	24
25	03/06/2003	REQUEST FOR EXTENSION OF TIME - GRANTED			
24	11/06/2002	MAIL NON-FINAL REJECTION			
23	11/04/2002	NON-FINAL REJECTION			
22	10/15/2002	DATE FORWARDED TO EXAMINER			
21	10/08/2002	RESPONSE TO ELECTION / RESTRICTION FILED			
20	10/08/2002	REQUEST FOR EXTENSION OF TIME - GRANTED			
19	08/08/2002	MAIL RESTRICTION REQUIREMENT	200		-1
18	08/08/2002	X-POST-LEGAL COMPLETE REJECTION			
17	08/08/2002	REQUIREMENT FOR RESTRICTION / ELECTION			
16	05/22/2002	CASE DOCKETED TO EXAMINER IN GAU			
15	02/20/2002	X-PRE-LEGAL COMPLETE NEW CASE			
14	12/10/2001	CASE DOCKETED TO EXAMINER IN GAU			
13	12/06/2001	CASE DOCKETED TO EXAMINER IN GAU			
12	10/26/2001	INFORMATION DISCLOSURE STATEMENT (IDS) FILED			
11	09/18/2001	INFORMATION DISCLOSURE STATEMENT (IDS) FILED			
10	05/18/2001	PRELIMINARY AMENDMENT			
9	11/06/2001	CASE DOCKETED TO EXAMINER IN GAU			
8	08/21/2001	APPLICATION DISPATCHED FROM OIPE			
7	08/10/2001	APPLICATION IS NOW COMPLETE		113	4
6	08/06/2001	CORRESPONDENCE ADDRESS CHANGE			
5	06/21/2001	CRF IS GOOD TECHNICALLY / ENTERED INTO DATABASE			
4	01/19/2001	NOTICE MAILED--APPLICATION INCOMPLETE-- FILING DATE ASSIGNED			
3	01/19/2001	CORRESPONDENCE ADDRESS CHANGE			
2	12/12/2000	IFW SCAN & PACR AUTO SECURITY REVIEW			
1	11/20/2000	INITIAL EXAM TEAM NN			

Search Another: Application#

### EXPLANATION OF PTA CALCULATION

### EXPLANATION OF PTE CALCULATION

## Patent Term Adjustment Calculation System

Add a new event to this case

Docket Number: 077281-0104

Application Number: 09/715036

Patent Number: N/A

	Event Description	Event Date	Days from Filing	PTO Days	Applicant Days
Edit Delete	Application Filing Date	11/20/2000	0		
Close Window	ALL CASES MISSING PARTS	01/19/2001	60		
Edit Delete	Notice to File Missing Parts	04/19/2001	150		
	Notice to File Missing Parts + 3 months	05/18/2001	179		29
Edit Delete	Response to Notice to File Missing Parts	01/20/2002	426		
	14 month From Application date	08/08/2002	626	200	
Edit Delete	Restriction Requirement	10/08/2002	687		
Edit Delete	Restriction Requirement Response Received at PTO	11/06/2002	716		
Edit Delete	Non-Final Office Action	02/06/2003	808		
	Non-Final Office Action + 3 months	03/06/2003	836		28
Edit Delete	Non-Final Office Action Response Received at PTO	06/04/2003	926		
	Final Office Action	09/04/2003	1,018		
	Final Office Action + 3 months	09/25/2003	1,039		
Edit Delete	Final Office Action Response Received at PTO	10/15/2003	1,059		
Edit Delete	Advisory Action	12/04/2003	1,109		91
Edit Delete	Request For Continued Examination	02/20/2004	1,187		
Edit Delete	Non-Final Office Action	03/17/2004	1,213		
	Non-Final Office Action Response Received at PTO	06/02/2004	1,290		
Edit Delete	Notice of Allowance	08/30/2004	1,379		
Edit Delete	Issue Fee Paid	12/30/2004	1,501		
	Issue Fee Paid + 4 months	09/13/2005	1,758	257	
Edit Delete	Patent Grant Date				
				Totals:	457
				PTA:	309
					148

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